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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,739	02/09/2004	Dean A. Schaefer	1001.1386102	9215

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EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
10/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,739	SCHAEFER ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-20 and 22-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-20, 22-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment filed on 09/16/10 has been entered.

Claims 16-20, 22-32 are present for examination.

Claims 1-15, 21 and 33-36 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-20, 22, 24, 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable by Webster, Jr. (US 5,057,092) in view of Fish (US 5,006,291).

Regarding claim 16, Webster discloses a catheter comprising: an elongate shaft 12 including an inner polymer layer 22 defining a lumen of the elongate shaft; a reinforcement layer (including 24, 26, 28) disposed about the inner polymer layer, and an outer polymer layer 30 disposed about the reinforcement layer, the reinforcement layer comprising a tubular braid having a first helical member 24 interwoven with a second helical member 26, and a plurality of axial members 28 disposed between the first helical member and the second helical member in some of plurality of crossover points but not each of the plurality of crossover points as in claim 16.

As seen in Figs. 2 or 5, the plurality of axial members 28 are attached at the distal end of inner layer 22 and the proximal end of inner layer 22 (not shown); the axial members 28 are made out of material with a level of flexibility, in which they allows for movement in relation to inner and outer polymer layers. Therefore, the plurality of axial members 28 are not fixed to the inner polymer layer and the outer layer such that the plurality of axial members is moveable relative to the inner polymer layer and the outer polymer layer.

Fish discloses a reinforced plastic tubing comprises a first helical member 26 interwoven with a second helical member 28, and a plurality of axial member 29 disposed between the first helical members 26 and the second helical member 28 at each of the plurality of crossover points, see Fig. 4.

Applicant also admitted that if the axial members 34 were positioned under or over the helical members 32A and 32B, the inner layer 38 or the outer layer 30 may become fixed to the axial members 34, thereby limiting relative movement and flexure there between…By positioning the axial members 34 between the helical members 32A and 32B, relative movement there between is permitted thereby maintaining some amount of flexibility. See pg 13, lines 6-13 of Specification.

Similarly, Fish suggests the arrangement of first, second helical members and the axial members are same as the claimed invention (i.e. the axial members disposed between the first and second helical member at each of the plurality of crossover points. Therefore, the pluralities of axial members are not fixed and movable to maintain some amount of flexibility.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster with a interwoven cross construction, as taught by Fish, in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility.

However, Webster further discloses that the workers skill in the art and technology to which this invention pertains will appreciate the alterations and changes in described apparatus can be practiced without meaning fully departing from the principals spirits and scope of the his invention (col. 4, lines 17-22).

It would have been an obvious matter of design choice to provide the axial member with different arrangement such as disposed between the first and second helical member at each of the plurality of cross over point. Therefore, it appears that the invention would perform equally well with device of Webster.

Regarding claim 17, the axial members are uniformly spaced about the circumference to the shaft.

Regarding claims 18-19, Webster in view of Fish discloses the claimed invention (see rejection above). Webster in view of Fish does not clearly show that four axial members are uniformly spaced apart

by 90° about the circumference of the shaft; eight axial members are uniformly spaced apart by 45° about the circumference of the shaft. It would have been an obvious matter of design choice to provide the axial members as listed above, since applicant has not disclosed that the number of axial members spaced apart by 45° or 90° solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device of Webster.

Regarding claim 20, Webster discloses, in Fig. 1, the elongate shaft includes a proximal portion and a distal portion, and wherein the distal shaft portion has fewer axial members 28 than the proximal shaft portion.

Furthermore, it is noted that those skilled in the art will recognize that if an inner diameter of the proximal shaft is larger than an inner diameter of distal shaft portion will give the same result that the distal shaft portion has fewer axial members than the proximal shaft portion.

For example, Head (US 6,148,865) is one of evidence shows that the distal shaft portion has fewer the axial members 22 the proximal shaft (see Fig. 3A); or Osborne (US 5,251,640) shows that the distal shaft portion has fewer the axial members 12 the proximal shaft (Figs. 1-5).

Not only that, the cross section area or diameter of distal portion of catheter is smaller than proximal portion is very well-known in the catheter art for easy to manipulate or insert into the body.

It would have been an obvious matter of design choice to provide the axial members as listed above, since applicant has not disclosed that the number of axial members solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device of Webster.

Regarding claims 22 and 24, the first and second helical members each comprise polymer material (col. 2, lines 54-65).

Regarding claim(s) 29-32, they encompass the same scope of the invention as to that of claims 16-19 above except they are drafted in method format instead of apparatus format. The claim(s) is/are therefore rejected for the same reason as set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent Nos. 6,709,429.

Claims 16, 22-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-9, 11, 13-28 of U.S. Patent Nos. 6,942,654.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the device and method of instant claims are fully disclosed and covered by the claims in the U.S. patents. 6,709,429 and 6,942,654.

Response to Arguments

Applicant's arguments filed 05/13/10 have been fully considered but they are not persuasive.

1. Applicant argues that nowhere Webster or Fish discloses that the plurality of axial members are not fixed to the inner polymer layer and the outer polymer layer such that the plurality of axial members are movable relative to the inner polymer layer and the outer polymer layer".

In response, first of all, the axial member 28 of Webster is made out of material with a level of flexibility, in which it allows for movement in relation to inner and outer polymer layer.

Second, Applicant admitted that if the axial members 34 were positioned under or over the helical members 32A and 32B, the inner layer 38 or the outer layer 30 may become fixed to the axial members 34, thereby limiting relative movement and flexure there between…By positioning the axial members 34 between the helical members 32A and 32B, relative movement there between is permitted thereby maintaining some amount of flexibility. See pg 13, lines 6-13 of Specification. (Emphasis added).

Similarly, Fish discloses the arrangement of first, second helical members and the axial members are same as the claimed invention (i.e. the axial members disposed between the first and second helical member at each of the plurality of crossover points). Therefore, the arrangement of pluralities of axial members between the two helical members of Fish is movement there between and permitted thereby maintaining some degrees of flexibility. Thus, the arrangement of the axial member is inherently not fixed and movable to maintain some amount of flexibility.

Third, since the arrangement of helical members and axial member of Fish is exactly same as the structure of claimed invention (i.e. the axial members disposed between the first and second helical member at each of the plurality of crossover points), if Applicant believes Fish does not disclose the plurality of axial members are not fixed to the inner and outer polymer layers, then the axial members of claimed invention are not fixed to the inner and outer polymer layers.

Fourth, Applicant is requested to provide evidence that the axial members of Webster and Fish are not fixed to the inner polymer layer and the outer polymer layer such that the plurality of axial members are movable relative to the inner polymer layer and the outer polymer layer.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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